

Applicant : Short, et al.
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Atty's Docket No.: 56446-20109.00/910001/
D1590-2US/2

REMARKS

Status of the Claims

Pending claims

Claims 33 to 37, 114, 115 and 132 to 192 are pending (claims 113 to 131 were added in a preliminary amendment, and, claim 132 to 192 were added in the response to the restriction requirement).

Claims added and deleted

In the instant amendment, claims 32, 33, 36, 37, 41, 42, 155 to 188, are deleted, without prejudice, and claims 193 to 200 are added. Accordingly, after the entry of the instant amendment, claims 31, 34, 35, 114, 115, 132 to 154, and 189 to 200 will be pending and under examination.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the new and amended claims. For example, support for claims directed to methods for making a protein polymer by self-assembly of monomers, wherein the protein polymer can comprise a nanoscale delivery vehicle, can be found, inter alia, on page 13, line 22 to page 14, line 14.

Support for claims directed to methods for making a polypeptide polymer made by self-assembly of monomers, wherein at least one monomeric polypeptide further comprises one or more enzymes, can be found, inter alia, on page 108, lines 14 to 19 (emphasis added):

Attaching one or more enzymes, which catalyze synthesis in a pathway, to one or more of the monomeric polypeptide units in the polymer of the present invention may provide a high-density immobilized, stable, economical biocatalyst for high value chemicals and pharmaceuticals. This type of immobilized biocatalyst may be removed and recycled or destroyed in a controlled way using simple chemical or enzymatic proteolysis.

Support for claims directed to methods for making a polypeptide polymer made by self-assembly of monomers, wherein at least one monomeric polypeptide further comprises a nucleotide or a nucleotide derivative, or a lipid or a lipid derivative, can be found, inter alia, in the paragraph from page 7, line 25 to page 8, line 7 (emphasis added):

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The term "polypeptide" as used herein, refers to amino acids joined to each other by peptide bonds or modified peptide bonds, i.e., peptide isosteres, and may contain modified amino acids other than the 20 gene-encoded amino acids. The polypeptides may be modified by either natural processes, such as post-translational processing, or by chemical modification techniques which are well known in the art. Modifications can occur anywhere in the polypeptide, including the peptide backbone, the amino acid side-chains and the amino or carboxyl termini. It will be appreciated that the same type of modification may be present in the same or varying degrees at several sites in a given polypeptide. Also a given polypeptide may have many types of modifications.

Modifications include acetylation, acylation, ADP-ribosylation, amidation, covalent attachment of flavin, covalent attachment of a heme moiety, covalent attachment of a nucleotide or nucleotide derivative, covalent attachment of a lipid or lipid derivative, covalent attachment of a phosphatidylinositol, cross-linking cyclization, disulfide bond formation, demethylation, formation of covalent cross-links, formation of cysteine, formation of pyroglutamate, formylation, gamma-carboxylation, glycosylation, GPI anchor formation, hydroxylation, iodination, methylation, myristoylation, oxidation, pegylation, proteolytic processing, phosphorylation, prenylation, racemization, selenoylation, sulfation, and transfer-RNA mediated addition of amino acids to protein such as arginylation.

Support for claims directed to methods for making a polypeptide polymer made by self-assembly of monomers, wherein at least one monomeric polypeptide further comprises a "targeting vector", such as an antibodies, oligosaccharides, and MorphatidesTM, can be found, inter alia, in the paragraph from page 90, line 14 to page 91, line 24 (emphasis added):

In order to better direct the nanoscale drug delivery vehicle or polymer of the present invention to a particular desired location in an animal body, a targeting vector may be attached to the polymer or the monomeric polypeptide of the present invention. The targeting vector useful in the present invention includes antibodies, oligosaccharides, and MorphatidesTM. All of these targeting vectors may be readily attached to the monomeric polypeptide surface using conventional chemistries. Antibodies are the most common targeting vectors but oligosaccharides have also been shown to function as effective targeting moieties.

The Restriction Requirements and Elections

In the restriction requirement mailed September 30, 2003, the Patent Office alleged that the pending claims of the application are directed to twenty-three (23) separate and distinct inventions under 35 U.S.C. §121. In the response to the group restriction requirement

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(mailed October 29, 2003), Applicants elected with traverse Group III, claims 31 to 37, 114 and 115, drawn to a method of producing a polypeptide polymer.

In the restriction requirement mailed September 30, 2003, the Patent Office further alleged that each restriction group reads on a plurality of independent and/or patentably distinct sequences, SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, or SEQ ID NO:9, for polynucleotides, and SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, or SEQ ID NO:10 for polypeptides. In response to the sequence restriction requirement, Applicants elected with traverse SEQ ID NO:2.

In the Communication of January 15, 2004, the Patent Office alleged that in view of the amendment to claim 31, the following election of species is required: (i) polymerizing the monomeric polypeptides through a self-assembly process, or, (ii) polymerizing the monomeric polypeptides in the presence of a template molecule. In response to the species restriction requirement, Applicants elected (i) polymerizing the monomeric polypeptides through a self-assembly process.

CONCLUSION

It is believed that the all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If an additional fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 03-1952. Please credit any overpayment to the above-noted Deposit Account.

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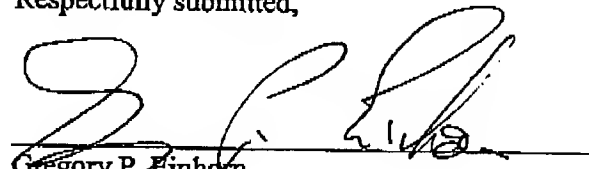
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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858 720 5133.

Respectfully submitted,

Date:

April 28, 2004


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